# LOUISIANA DEPARTMENT OF HEALTH AND DEPARTMENT OF CORRECTIONS

# **HEPATITIS C INNOVATIVE PAYMENT MODEL**

**CONTRACT WITH** 

**ASEGUA THERAPEUTICS LLC** 

**EFFECTIVE JULY 1, 2019** 

This contract is effective July 1, 2019, by and between the LOUISIANA DEPARTMENT OF HEALTH (LDH), duly represented by its Office of Public Health (OPH) and the Bureau of Health Services Financing (LDH/MEDICAID), the LOUISIANA DEPARTMENT OF CORRECTIONS (DOC), and ASEGUA THERAPEUTICS LLC (ASEGUA), a wholly owned affiliate of Gilead Sciences, Inc., hereafter collectively referred to as "the parties", related to the implementation of a Hepatitis C Innovative Payment Model Contract as a result of a Solicitation for Offers (SFO).

WHEREAS, Louisiana is facing a public health crisis caused by caused by Hepatitis C (HCV), the deadliest infectious disease in the United States;

WHEREAS, this crisis can be addressed by providing curative treatment to those who are infected utilizing direct-acting antivirals (DAA);

WHEREAS, due to the high cost of DAA treatment and the budget limitations of States, States are looking for innovative ways to provide access to infected individuals in order to eliminate this disease;

WHEREAS, Louisiana has a high number of residents who are currently infected with HCV; a large portion of those individuals are LDH/Medicaid recipients (hereinafter referred to as the "Medicaid Population"), or are detained within forensic facilities or a part of the State offender population, convicted of a felony and sentenced to the custody and control of DOC and housed in either state or local (Parish) correctional facilities (hereinafter referred to as the "Incarcerated Population"). Moreover, the rate of new infections is growing dramatically as a result of injection drug use associated with the opioid epidemic;

WHEREAS, LDH/Medicaid and DOC have set a goal to eliminate HCV within the Medicaid Population and Incarcerated Populations within 5 years while limiting net expenditures on DAAs to the Total State Spend for Fiscal Year 2018 in both the Medicaid Population and Incarcerated Populations;

WHEREAS, LDH/Medicaid and DOC issued a Solicitation for Offers (SFO) on January 10, 2019, seeking a partner for implementing an HCV subscription model in order to accomplish the above goal;

WHEREAS, ASEGUA was selected as the winning proposer and has agreed to provide unlimited access to its authorized generic for EPCLUSA (sofosbuvir/velpatasvir), hereafter referred to as agSOF/VEL, while partnering with the State to limit the expenditures of LDH/Medicaid and the DOC to specific levels;

WHEREAS, since the LDH/Medicaid program utilizes managed care organizations (MCO) to provide pharmaceutical benefits to recipients and does not directly reimburse any pharmaceutical manufacturer, the limitation of net expenditures within LDH/Medicaid will be accomplished through the use of a State Supplemental Rebate Agreement (SRA) and the Medicaid Preferred Drug List (PDL);

WHEREAS, since DOC provides pharmaceutical benefits to the Incarcerated Population through a partnership with a 340B covered entity, the parties intend to utilize 340B pricing in order to limit expenditures within that population; and

WHEREAS, as the winning proposer, ASEGUA will partner with LDH/Medicaid and DOC to provide certain other complementary public health elimination strategies as referenced in this contract below.

NOW, after due consideration from the parties, which all parties acknowledge as received, the parties agree as follows:

### Article 1 – SCOPE OF INNOVATIVE PAYMENT MODEL

- 1. By entering into this contract, the parties intend to implement an innovative payment (i.e. an expenditure cap) model for the Medicaid Population and for the Incarcerated Population, each for the provision of an unlimited supply of agSOF/VEL for the treatment of HCV. The goal of these models is to eliminate HCV infections in the Medicaid Population and the Incarcerated Population. The innovative payment model are premised on four key aspects: (1) unrestricted availability of agSOF/VEL for purchase by pharmacies, (2) provision of state supplemental rebates by ASEGUA in order to limit LDH/Medicaid expenditures, (3) utilization of a 340B "covered entity" for the treatment of the Incarcerated Population, and (4) complementary public health elimination strategies implemented by the parties through partnership including expanding provider capacity, educating the public on availability of DAAs and mobilizing priority populations for screening, expanding the HCV screening and linkage to cure, strengthening HCV surveillance, and implementing harm reduction and complementary treatment strategies.
- 2. Within its managed care setting, LDH/Medicaid provides a Per Member Per Month (PMPM) payment to MCOs who are then fully at risk for covering LDH/Medicaid services for their enrollees. The MCOs pay for these services through their provider networks, which include pharmacies. In a pharmacy context, the pharmacy fills the prescription presented and receives reimbursement from the MCO in accordance with the MCO contract with LDH/Medicaid. In the LDH/Medicaid fee-for-service (FFS) program, LDH/Medicaid reimburses the pharmacy providers enrolled in LDH/Medicaid pursuant to its approved State Plan.
  - LDH/Medicaid maintains a PDL that provides uniform access to agSOF/VEL across both delivery systems, FFS and MCO.
- 3. Clinical services for the Incarcerated Population are provided by LSU Lallie Kemp Regional Medical Center, a 340B covered entity (the "Clinical Services Provider"). The 340B Drug Pricing Program enables covered entities to purchase covered outpatient drugs at discount pricing, and such purchases are excluded from a manufacturer's "best price" for such product. Thus, as a result of the Clinical Services Provider's 340B covered entity status and compliance with all applicable eligibility requirements of the 340B statute, any drugs it purchases are excluded from ASEGUA's "best price" for agSOF/VEL. With the innovative payment model, the 340B covered entity Clinical Services Provider will purchase agSOF/VEL for the Incarcerated Population at the applicable 340B ceiling price up to an annual expenditure amount to limit DOC's expenditures.

# <u>Article 2 – LDH/Medicaid Obligations, Warranties, and Representations</u>

- 1. PDL Listing For the term of this contract, subject to limitations specified herein, LDH/Medicaid agrees to list agSOF/VEL as the exclusive preferred HCV DAA on the LDH/Medicaid PDL. Specifically, agSOF/VEL will be listed as the exclusive preferred drug for the treatment of HCV in adult patients with chronic HCV infection of genotype 1, 2, 3, 4, 5, or 6.
- 2. Removal of Clinical Pre-authorization for the Therapeutic Preferred Product In the PDL process, LDH/Medicaid applies a clinical pre-authorization to certain therapeutic classes. In practice, this clinical pre-authorization takes a similar form as other prior authorizations, but is applied to all

drugs in a therapeutic class, both preferred and non-preferred. It requires the prescriber to demonstrate that the drug is medically necessary for the patient by submitting an authorization form which is then reviewed for applicable criteria. For the term of this contract, subject to limitations specified herein, LDH/Medicaid agrees to lift the clinical pre-authorization for agSOF/VEL, with prior authorization requiring a documented failure of agSOF/VEL remaining for all other DAAs, unless the patient satisfies medical necessity of the preferred product.

- 3. Simplified Access to agSOF/VEL for LDH/Medicaid Prescribers and Members By lifting the clinical pre-authorization requirement for agSOF/VEL and listing agSOF/VEL as the sole preferred drug for treatment of HCV infection, LDH/Medicaid is removing several existing restrictions. With a valid prescription, LDH/Medicaid recipients with pharmaceutical benefits will be able to fill a prescription for agSOF/VEL with no prior authorization, regardless of fibrosis stage, attestation of abstention from substance use, or any other clinical characteristic.
- 4. Limitations LDH/Medicaid reserves the right to remove "preferred" status for agSOF/VEL, reimpose the clinical pre-authorization requirement for the therapeutic class, or both, for any of the following reasons:
  - a. ASEGUA does not provide for, and remit payment of, State Supplemental Rebates for the use of agSOF/VEL to the Louisiana LDH/Medicaid Program at the contractually negotiated levels.
  - b. ASEGUA does not provide through its authorized distributors, at all times during the effective term of this contract, an unrestricted supply of agSOF/VEL to enrolled pharmacies serving the Medicaid Population and the Incarcerated Population for the treatment of HCV.

c.

The list of ASEGUA

authorized distributors for agSOF/VEL is set forth at <a href="https://www.asegua.com/authorized-generic-therapies">https://www.asegua.com/authorized-generic-therapies</a>.

- d. The federal government rescinds approval for agSOF/VEL as a treatment for chronic HCV across genotypes 1-6.
- e. In the event that ASEGUA is determined, by an appropriate regulatory body or court of competent jurisdiction, to be in violation of state or federal law or regulation in performing any of its duties as specified in this contract, LDH/Medicaid shall have the right to immediately terminate this contract upon written notice to ASEGUA; provided, however, if such violation if curable, ASEGUA will have the opportunity to cure any such violation during a period of no less than ninety (90) days, and LDH/Medicaid may enter into a compliance plan with ASEGUA in lieu of termination.
- 5. LDH/Medicaid, in accordance with all applicable federal laws and regulations, will provide for coverage of agSOF/VEL to the Medicaid Population as long as ASEGUA complies with federal Medicaid Drug Rebate Program requirements. For clarity, the Medicaid Population includes all individuals enrolled or eligible to enroll in the Louisiana Medicaid Program as described in

Louisiana's CMS-approved State Medicaid State Plan. LDH/Medicaid will continue to require that LDH/Medicaid MCOs reimburse pharmacy providers in the usual and customary manner. Further, in a FFS setting, LDH/Medicaid will continue to reimburse pharmacies in accordance with its Centers for Medicare and Medicaid Services (CMS)-approved State Plan.

LDH/Medicaid will, at all times during this contract, act in good faith and will not take any actions to materially limit HCV treatment access during the term of this contract. Further, LDH/Medicaid commits that it will actively seek to screen, link and treat as many patients as possible. However, LDH/Medicaid expressly does not guarantee any specific numbers of individuals would seek and / or receive treatment with agSOF/VEL over the term of this contract.

- 6. Public Records If LDH/Medicaid receives a public records request to which it believes information contained in ASEGUA's response to the SFO or this contract to be responsive and subject to disclosure, LDH/Medicaid will provide notice to ASEGUA and provide a reasonable time for ASEGUA to seek a protective order from a Court of Competent Jurisdiction or object to the release and shall comply with all applicable laws and regulations, including without limitation the Louisiana Public Records Act. This provision applies to records that are owned by ASEGUA that are provided to LDH/Medicaid and which ASEGUA believes are confidential / proprietary ONLY. The parties acknowledge that ASEGUA considers the financial terms under this Contract to be exempt from disclosure under the Louisiana Public Records Act.
- 7. LDH/Medicaid represents and warrants that, at all times during the term of this contract, it will adhere to all applicable federal and state regulations, statutes, and rules. If LDH/Medicaid receives any notice or information that confirms it no longer meets the warranty and representations in this paragraph, it will immediately notify ASEGUA in writing.

# Article 3 – DOC Obligations, Warranties, and Representations

- 1. DOC will, at all times during this contract, act in good faith and will not take any actions to materially limit HCV treatment access during the term of this contract.
- 2. Further, DOC commits that it will actively seek to screen, link and treat as many patients as possible. However, DOC expressly does not guarantee the screening and or treatment of any specific number of individuals.
- 3. Limitations DOC reserves the right to cease utilization of agSOF/VEL within the Incarcerated Population for any of the following reasons:
  - a. ASEGUA, for any reason whatsoever, is no longer able to utilize and provide agreed upon 340B pricing of agSOF/VEL for the treatment of the Incarcerated Population.
  - b. ASEGUA does not provide through its authorized distributors, at all times during the effective term of this contract, an unrestricted supply of agSOF/VEL to DOC for use within the Incarcerated Population. The list of ASEGUA authorized distributors for agSOF/VEL is set forth at https://www.asegua.com/authorized-generic-therapies.

- c. The federal government rescinds approval for agSOF/VEL as a treatment for chronic HCV across genotypes.
- 4. In the event that ASEGUA is determined, by an appropriate regulatory body or court of competent jurisdiction, to be in violation of state or federal law or regulation in performing any of its duties as specified in this contract, DOC shall have the right to immediately terminate this contract upon written notice to ASEGUA provided, however, if such violation if curable, ASEGUA will have the opportunity to cure any such violation during a period of no less than ninety (90) days, DOC may enter into a compliance plan with ASEGUA in lieu of termination.
- 5. Public Records If DOC receives a public records request to which it believes information contained in ASEGUA's response to the SFO or this contract to be responsive and subject to disclosure, DOC will provide notice to ASEGUA and provide a reasonable time for ASEGUA to seek a protective order from a Court of Competent Jurisdiction or object to the release and shall comply with all applicable laws and regulations, including without limitation the Louisiana Public Records Act. This provision applies to records that are owned by ASEGUA that are provided to DOC and which ASEGUA believes are confidential / proprietary ONLY. The parties acknowledge that ASEGUA considers the financial terms under this Contract to be records exempt from disclosure under the Louisiana Public Records Act.
- 6. DOC represents and warrants that, at all times during the term of this contract, it will adhere to all applicable federal and state regulations, statutes, and rules. If DOC receives any notice or information that confirms it no longer meets the warranty and representations in this paragraph, it will immediately notify ASEGUA in writing.

# ARTICLE 4 – ASEGUA Obligations, Warranties, and Representations

- 1. ASEGUA specifically warrants that it is a Delaware limited liability company that is a 100% owned subsidiary of Gilead Sciences, Inc. (Gilead). Further, ASEGUA warrants that it has full authority to market and distribute agSOF/VEL to LDH/Medicaid and DOC.
- 2. ASEGUA shall warrant that it, its officers, and its employees have no interest and shall not acquire any interest, direct or indirect, which conflicts in any manner or degree with the performance of services hereunder. If ASEGUA subsequently becomes aware of any of its officers and employees acquiring such conflicts, it shall inform LDH/Medicaid promptly of any such conflict.
- 3. In addition, ASEGUA warrants and represents that it will not, at any time during the term of this contract, knowingly employ any individual providing work under this contract that has a conflict of interest with LDH/Medicaid or DOC. If the LDH/Medicaid or DOC suspects that a conflict of interest may exist, they will notify ASEGUA in writing. Within thirty (30) days of receipt of such notification, ASEGUA will inform the LDH/Medicaid and DOC, in writing, of the results of any investigation or the reasons why, in their opinion, an investigation was not merited.

- 4. ASEGUA shall provide through its wholesale distributors enrolled LDH/Medicaid pharmacy providers and DOC with access to an unlimited supply of agSOF/VEL to allow for treatment of the Medicaid Population and the Incarcerated Population while this contract is in effect.
- 5. ASEGUA specifically warrants that agSOF/VEL is FDA approved and clinically indicated for the treatment of adult patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infection. ASEGUA further warrants that in clinical trials, agSOF/VEL has demonstrated high sustained virologic response rates, up to 98% overall, across chronic HCV patients with GT 1-6 including treatment-naïve, treatment experienced, non-cirrhotic, and compensated cirrhotic patients.

6.

- 7. ASEGUA warrants and represents that it is in good legal standing and authorized to conduct business in the State of Louisiana. ASEGUA represents and warrants that, at all times during the term of this contract, it will adhere to all applicable federal and state regulations, statutes, and rules. If ASEGUA receives any notice or information that confirms it no longer meets the warranty and representations in this paragraph, it will immediately notify LDH/Medicaid and DOC in writing.
- 8. In consideration for having agSOF/VEL placed on the LDH/Medicaid PDL as the exclusive "preferred" pharmaceutical for the treatment of HCV and for removing the clinical preauthorization requirement, ASEGUA hereby expressly agree to enter into a supplemental rebate agreement in substantially the form attached hereto as Appendix A (SRA), with LDH/Medicaid. The parties agree that the express purpose of this SRA is to limit LDH/Medicaid expenditures for the treatment of the LDH/Medicaid population with agSOF/VEL at agreed upon levels. ASEGUA's obligation to enter into the SRA is conditioned upon CMS approval of such SRA by State Plan Amendment.

- 9. At no time will LDH/Medicaid make payments directly to ASEGUA for the provision of agSOF/VEL. All LDH/Medicaid reimbursement will be made by LDH/Medicaid directly to LDH/Medicaid MCOs or directly to LDH/Medicaid-enrolled pharmacies in accordance with the LDH/Medicaid CMS-approved State Plan. The pharmacy reimbursement and supplemental rebate process is detailed in Article 5.
- 10. In further consideration for having agSOF/VEL placed on the DOC formulary as the exclusive "preferred" pharmaceutical for the treatment of HCV, and for removal of the clinical preauthorization requirement for agSOF/VEL, ASEGUA agrees to provide an unlimited supply of agSOF/VEL to DOC to be utilized in treating HCV in the Incarcerated Population pursuant to a 340B discount agreement with the Clinical Services Provider ("340B Discount Agreement"), to be negotiated and agreed to between ASEGUA and the Clinical Services Provider. The parties acknowledge that DOC has an existing clinical services agreement with the Clinical Services Provider for the provision of direct medical care to the Incarcerated Population within DOC custody. The parties shall amend this Contract to attach the 340B Discount Agreement Appendix B, which shall be incorporated and made a part of this contract.

For the avoidance of doubt, the price per unit of agSOF/VEL purchased by the Clinical Services Provider to treat the Incarcerated Population in that Louisiana State Fiscal Year shall not exceed the applicable 340B ceiling price calculated in accordance with 42 U.S.C. §256b(a).

- 11. ASEGUA will hold weekly calls with the LDH/Medicaid and DOC for the first three months of the project implementation and will hold monthly calls thereafter for the duration of the contract. The frequency of such calls may be modified upon mutual agreement of the parties. ASEGUA will be responsible for maintaining the agendas and minutes from these meetings and managing implementation of ASEGUA's obligations from these meetings. Should urgent supply chain or other issues arise between scheduled meetings, LDH/Medicaid, DOC and ASEGUA will each designate a method for contact with a response within 1 business day.
- 12. ASEGUA will provide, through its affiliate Gilead, initiatives designed to further the elimination of HCV in Louisiana consistent with Gilead's efforts across the country, which support the complementary strategies that comprise Louisiana's Hepatitis C Elimination Plan, including but not limited to any and all activities outlined in ASEGUA's proposal. The parties acknowledge that these programs were created and implemented independently of this Contract and will continue to be provided in Louisiana regardless of the status of this Contract. Such initiatives include but are not limited to:

- a. Providing education to providers, including without limitation LDH/Medicaid and DOC clinicians and support staff, regarding how to effectively screen, test and treat hepatitis C in these populations.
- b. Developing, promoting and publishing educational materials for the public, including without limitation the Medicaid Population and Incarcerated Population, on the importance of screening, treatment, medication adherence and strategies designed to reduce the risk of reinfection.
- c. Expanding HCV screening and expedited linkage to HCV Cure, strengthening HCV surveillance to link persons previously diagnosed to treatment,
- d. Promoting elimination efforts statewide by educating private insurers on the costeffectiveness of screening, treating and curing hepatitis C infection.

# <u>Article 5 – LDH/Medicaid Pharmacy Reimbursement and Supplemental Rebate Agreements</u>

- 1. In the FFS program, LDH/Medicaid reimburses pharmacy providers pursuant to its CMS approved State Plan.
- 2. In the managed care program, Louisiana LDH/Medicaid provides MCOs a PMPM payment that is fully capitated to pay MCOs for reimbursement of MCO network pharmacy providers for dispensing pharmaceuticals to MCO enrollees, including agSOF/VEL. Nothing herein shall limit or otherwise prevent LDH/Medicaid's ability to utilize kick payments to reimburse the MCOs for utilization of these drugs to treat chronic hepatitis C infection.

3.

4. To ensure that annual expenditures do not exceed the above expenditure limit, the parties agree to utilize a tracking and rebate system as follows:

- 5. In regards to the Incarcerated Population:
  - a. The parties understand and agree that clinical services will be provided by DOC to the Incarcerated Population by the Clinical Services Provider, a 340B covered entity, that will distribute agSOF/VEL to its patients.
  - b. ASEGUA will negotiate a 340B Discount Agreement to administer pricing and provide an unlimited supply of agSOF/VEL to the Incarcerated Population consistent with the applicable terms set forth in this Contract.

#### Article 6 – Term and Termination Provisions

- 1. The term of this Contract is five (5) years from the Effective Date. The Effective Date shall be July 1, 2019.
- 2. The Contract can only be terminated prior to June 30, 2024, as follows:
  - a. The parties may mutually agree in writing to terminate this Contract;
  - b. The Contract shall immediately terminate if the SRA is terminated or no longer in effect;
  - c. The Contract shall immediately terminate if the 340B Discount Agreement is terminated or no longer in effect;
  - d. Any party may terminate the Contract if another party is in material breach of the SRA;
  - e. Any party may terminate the Contract if another party is no longer materially complying with the applicable obligations, warranties and representations set forth in this Contract;
  - f. Any party may terminate the Contract if a significant change of, or interpretation of, any state or federal rules or regulations that materially impacts the performance by a party of any material obligation under this Contract would be rendered illegal or any material provision of this Contract would be rendered invalid or unenforceable and the parties are unable to negotiate a mutually acceptable amendment to this Contract that addresses the ability of such party to continue performance hereunder while preserving to the greatest extent possible the original intent of this Contract; or

#### ARTICLE 7: GENERAL PROVISIONS

#### 1. ASSIGNMENT

Neither party shall assign any interest in this Contract and shall not transfer any interest in same, whether by assignment or novation, without prior written consent of the other party, provided however, ASEGUA may assign or transfer its interests under this Contract, without such consent and by providing notice, to an affiliate; provided, further, that claims for money due or to become due to ASEGUA from the State of Louisiana (State) may be assigned to a bank, trust company, or other financial institution without such prior written consent. Notice of any such assignment or transfer shall be furnished promptly to the State. The parties acknowledge that Gilead, an affiliate of ASEGUA, will perform certain administrative and support functions for Asegua pursuant to an intercompany agreement, including the activities described in Article 4, Section 12.

#### 2. RESOLUTION OF DISPUTES

Any issues or provisions of the contract in dispute between the parties which, and in the judgment of any party, may materially affect the performance of such party, shall be reduced to writing and delivered to the other party. The parties shall promptly negotiate in good faith and use every reasonable effort to resolve such disputes in a mutually satisfactory manner within thirty (30) calendar days after receipt of such written notice. Nothing herein shall limit, restrict or otherwise supersede either party's right to terminate this Contract pursuant to Article 6 or to pursue any other rights or remedies to which it may be entitled under law or equity.

#### 3. AUDITOR'S CLAUSE AND RECORD RETENTION

- It is hereby agreed that the Legislative Auditor of the State of Louisiana, and/or the Division of Administration's auditors shall have the option of auditing all records and accounts of the other party which relate to this Contract.
- Each party and any subcontractors under this Contract shall maintain all books, records, and any other documents pertaining to or relevant this Contract and the funds expended hereunder for a period of five years after the date of final payment under the prime contract and any subcontract entered into under this Contract, or as required by applicable Federal law if Federal funds are used to fund this contract, whichever period is longer.
- It is hereby agreed that ASEGUA shall have the option of auditing all records and accounts of: (1) LDH/Medicaid which relate to rebates claimed under the SRA; and (2) DOC which relate to rebates claimed under the 340B Discount Agreement. Company may use a designated third-party auditor to conduct an audit hereunder, provided the designated auditor has signed a confidentiality agreement with ASEGUA.

#### 4. AMENDMENTS IN WRITING

Any alteration, variation, modification, or waiver of provisions of this Contract shall be valid only when it has been reduced to writing and executed by all parties.

# 5. DISCRIMINATION CLAUSE

ASEGUA agrees to abide by the requirements of the following as applicable: Title VI and VII of the Civil Rights Act of 1964, as amended by the Equal Opportunity Act of 1972, Federal Executive Order 11246, the Federal Rehabilitation Act of 1973, as amended, the Vietnam Era Veterans' Readjustment Assistance Act of 1974, Title IX of the Education Amendments of 1972, the Age Act of 1975, and ASEGUA agrees to abide by the requirements of the Americans with Disabilities Act of 1990. ASEGUA agrees not to discriminate in its employment practices, and will render services under this contract without regard to race, color, religion, sex, sexual orientation, age, national origin, disability, political affiliation, veteran status, or any other non-merit factor. Any act of discrimination committed by ASEGUA, or failure to comply with these statutory obligations when applicable shall be grounds for termination of this Contract.

#### 7. PARTIAL INVALIDITY; SEVERABILITY

If any term, covenant, condition, or provision of this Contract or the application thereof to any person or circumstances shall, at any time or to any extent, be invalid or unenforceable, the remainder of this Contract, or the application of such term, covenant, condition, or provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term, covenant, condition, and provision of this Contract shall be valid and be enforced to the fullest extent permitted by law.

#### 8. ENTIRE AGREEMENT; MODIFICATION

This Contract, including any attachments that are expressly referred to in this Contract, contains the entire agreement between the parties and supersedes any and all agreements or contracts previously entered into between the parties. No representations were made or relied upon by either party, other than those that are expressly set forth.

#### 9. CONTROLLING LAW

The validity, interpretation, and performance of this Contract shall be controlled by and construed in accordance with the laws of the State of Louisiana. Venue for any action brought with regard to this Agreement shall be in the Nineteenth Judicial District Court, Parish of East Baton Rouge, State of Louisiana. Contractor expressly agrees to exclude the Louisiana conflict of laws provisions.

#### 10. LEGAL COMPLIANCE

The State and/or Agency shall comply with all federal, state, and local laws and regulations, including, specifically, the Louisiana Code of Governmental Ethics (La. R.S. 42:1101 et seq.) in carrying out the provisions of this Contract.

#### 11. FORCE MAJEURE

Neither party to this Agreement shall be responsible to the other party hereto for any delays or failure to perform caused by any circumstances reasonably beyond the immediate control of the party prevented from performing, including, but not limited to, acts of God.

# 12. EMPLOYMENT OF STATE PERSONNEL; NO AGENCY

ASEGUA certifies that it has not employed and will not knowingly, after due diligence inquiry, employ any person to engage in the performance of this Contract who is, presently, or at the time of such employment, an employee of the State of Louisiana.

The Parties to this Contract herein acknowledge that each shall act in an independent capacity in the performance of their respective responsibilities under this Contract, and neither party is or is to be considered the officer, agent, or employee of the other.

#### 13. COVENANT AGAINST CONTINGENT FEES

ASEGUA warrants that it has not employed or retained any entity or person, other than a bona fide employee working solely for ASEGUA, to solicit or secure this Contract, and that it has not paid or agreed to pay any entity or person, other than a bona fide employee working solely for ASEGUA any fee, commission, percentage, brokerage fee, gift, or any other consideration, contingent upon or resulting from the award or making of this Contract. For breach or violation of this warranty, the State and/or Agency shall have the right to annul this Agreement without liability or, in State and/or Agency's discretion, to deduct from the contract price or consideration, or otherwise recover the full amount of such fee, commission, percentage, brokerage fee, gift, or contingent fee.

#### 14. NOTICES

All notices and other communications pertaining to this Agreement shall be in writing and shall be transmitted either by personal hand-delivery (and receipted for) or deposited in the United States mail, as certified mail, return receipt requested and postage prepaid, to the other party, addressed as follows:

If Notice to LDH:

Kimberly Sullivan LDH Deputy General Counsel P.O. Box 3836 Baton Rouge, LA 70821 225-342-0207 kimberly.sullivan@la.gov

If Notice to DOC:

Thomas C. Bickham, III
Undersecretary
Louisiana Department of Corrections
504 Mayflower
Baton Rouge, La 70802
225-342-6839

If Notice to ASEGUA:

Asegua Therapeutics LLC 333 Lakeside Drive Foster City, CA 94404 Attention:

With a copy to:

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 Attention: General Counsel

The Parties shall maintain telephone, in person, and/or e-mail communications (not limited to the Contact Persons designated in this Article 7, Section 14. Any change in the mailing address or contact person of ASEGUA is to be given to the State and/or Agency within seven (7) business days.

# 15. APPENDIX

All Appendices are attached and made a part of this Contract by reference.

16. This Contract is contingent upon receipt of any and all approvals needed by the Centers for Medicare and Medicaid Services including, but not limited to, the approval of any applicable State Plan Amendments, Supplemental Rebate Agreements, or any approvals necessary for utilization of 340B Drug Pricing for the treatment of the Department of Corrections population.

[Signature page follows.]

IN WITNESS WHEREOF, the parties have caused this Contract to be duly executed as of the dates set forth below.

# LOUISIANA DEPARTMENT OF HEALTH

# By: Name: Rebekah Gee, MD, MPH Title: Secretary Date June 25, 2019

# **ASEGUA THERAPEUTICS LLC**

Ву:	—pocusigned by: Existic Bawks
Name.	KHSTE BAKS
Title:	Authorized Person
Date	June 25, 2019

# **LOUISIANA DEPARTMENT OF CORRECTIONS**

By:	Thomas C. Bickham, III Diptally signed by Thomas C dicham, III of Department of Pub Safety & Corrections Correctio
Name:	Thomas C Bickham, III
Title:	•
Date	Undersecretary
	_June 25, 2019

# Appendix A

Supplemental Rebate Agreement

# Appendix B

340B Discount Agreement